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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,389	09/04/2001	Paul James Davis	IMIN.P-002-2	9864
21121	7590	07/26/2002	EXAMINER	
OPPEDAHL AND LARSON LLP P O BOX 5068 DILLON, CO 80435-5068			NGUYEN, BAO THUY L	
ART UNIT		PAPER NUMBER		
1641		13		
DATE MAILED: 07/26/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/944,389	DAVIS ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 20 May 2002.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 26-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 26-83 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1/2</u> | 6) <input type="checkbox"/> Other: _____                                     |

**DETAILED ACTION**

*Preliminary Amendment*

1. Applicant's preliminary amendment filed 5/20/2002 has been received. Claims 1-25 have been canceled. Claims 26-83 have been added and are pending.

*Priority*

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994).

3. Claims 26-82 have proper support in a parent application and will receive the earliest filing date to which they are entitled, 2/16/90. However, claim 83 does not have support in any of the priority documents and will receive the instant filing date, 9/4/2001.

*Information Disclosure Statement*

4. The information disclosure statement filed 9/04/01 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be

listed. It has been placed in the application file, but the information referred to therein *that has not been initialed* has not been considered.

5. For future reference, please review the IDS for any duplications prior to submission to eliminate any confusion. Please also place the references in numerical and/or alphabetical order to facilitate an efficient review of the references.

*Claim Rejections - 35 USC § 103*

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 26-36, 39-55, 58-74 and 77-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenstein (US 5,591,645) in view of Eisinger et al (US 4,943,522).

Rosenstein discloses an assay device comprising a solid support having a sample receiving portion connected to a porous carrier via a tracer portion (column 1, lines 42-67). Rosenstein teaches that the solid support is in the form of a strip with the first, second and third

portions being arranged on the strip in the same plane in a manner such that material can flow by capillary attraction from the first zone and through the second zone to the third zone (column 3, lines 51-59). Rosenstein teaches that the material of the solid support may be selected from the group comprising glass fiber, cellulose, nylon, crosslinked dextran, etc. (column 3, lines 39-49). Rosenstein teaches a sandwich assay format in which tracer is supported on a tracer portion of the solid support which is different from the first portion of the solid support. The ligand portion of the tracer is bound by the analyte, with the binder immobilized in the third portion of the solid support being specific the analyte. The first portion of the solid support is contacted with the sample containing analyte, and the tracer portion of the solid support is wetted to cause both the tracer and analyte to flow by capillarity to the immobilized binder. The amount of tracer that becomes bound to analyte is directly proportional to the amount of analyte in the sample. Any excess tracer is caught in another portion and may serve as a control (column 3, lines 7-27). Rosenstein teaches tracer comprising gold sols, liposomes and colored polystyrene particles (column 5, line 63 through column 6, line 21). The device of Rosenstein is suitable for detecting analytes such as hCG and leutinizing hormone (column 7, lines 27-38).

Rosenstein differs from the instant invention in failing to specifically teach that the tracer portion is a macroporous body and that the solid support is disposed within a housing.

Eisinger, however, discloses a device similar that of Rosenstein and the instant invention. Eisinger teaches the use of non-bibulous material in which the liquid flow is isotropic and flows laterally in the material by capillary action, providing a system in which the solid membrane does not imbibe or interfere with the specific binding reaction (column 4, lines 25-39). Eisinger teaches suitable material including polyethylene, polyvinyl chloride, and other

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thermoplastic material, etc. having pore sizes in an optimum range of 10  $\mu\text{m}$  to 50  $\mu\text{m}$  (column 6, line 56 through column 7, line 19). Eisinger also teaches a housing having appropriate apertures for observing test results (column 11, line 49 through column 12, line 36).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the tracer portion taught by Rosenstein with the macroporous membrane taught by Eisinger because Eisinger teaches that such material provides the advantage of an isotropic flow by capillary action, and thus preventing any possible interference with the specific binding reaction thereby improving results. It also would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Rosenstein by including a housing such as taught by Eisinger because such a housing provides the advantage of a protective cover for the solid support and reagents incorporated therein.

9. Claims 26-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over May et al (GB 2,204,398 A) in view of Eisinger.

May teaches an assay device comprising a hollow casing constructed of moisture-impervious solid material containing a dry porous carrier which communicates directly or indirectly with the exterior of the casing such that a liquid test sample can be applied to the porous carrier, the device containing a labeled specific binding reagent for an analyte which labeled specific binding reagent is freely mobile within the porous carrier when in the moist state, and unlabeled specific binding reagent for the same analyte which unlabeled reagent is permanently immobilized in a detection zone on the carrier material (page 3). May teaches an embodiment of the invention in which a dry porous nitrocellulose carrier communicates indirectly with the exterior of the casing via a bibulous urine receiving member which

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protrudes from the casing and which can act as a reservoir from which urine is released into the porous carrier (page 7, lines 23-29, see also figure 9 and description on page 23). The device also contains a control zone which is loaded with an antibody that will bind to the labeled antibody from the first zone. The control zone can contain an anhydrous reagent that when moistened, produces a color change or color formation. Or as an alternative, the control zone could contain immobilized analyte which will react with excess labeled reagents from the first zone (page 9). May teaches the use of direct labels such as minute colored particles, such as dye sols, metallic sols and colored latex particles (page 10). May teaches a plurality of detection zones arranged in series on the porous solid phase material through which the aqueous liquid sample can pass progressively, can also be used to provide a quantitative measurement of the analyte or can be loaded individually with different specific binding agents to provide a multi-analyte test (page 11). Quantitative measurement may be done visually by eye or by instrument (page 10, lines 10-13). May teaches a device incorporating two or more discrete bodies of porous solid phase material, each carrying mobile and immobilized reagent. These discrete bodies can be arranged in parallel such that a single application of liquid sample to the device initiates sample flow in the discrete bodies simultaneously (page 12, lines 6-20).

May differs from the instant invention in failing to teach the use of a macroporous body.

Eisinger, however, discloses a device similar that of Rosenstein and the instant invention. Eisinger teaches the use of non-bibulous material in which the liquid flow is isotropic and flows laterally in the material by capillary action, providing a system in which the solid membrane does not imbibe or interfere with the specific binding reaction (column 4, lines 25-39). Eisinger teaches suitable material including polyethylene, polyvinyl chloride, and other thermoplastic material, etc. having pore sizes in an optimum range of 10  $\mu\text{m}$  to 50  $\mu\text{m}$  (column

6, line 56 through column 7, line 19). Eisinger also teaches a housing having appropriate apertures for observing test results (column 11, line 49 through column 12, line 36).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the tracer portion taught by ~~Rosenstein~~ <sup>May</sup> with the macroporous membrane taught by Eisinger because Eisinger teaches that such material provides the advantage of an isotropic flow by capillary action, and thus preventing any possible interference with the specific binding reaction thereby improving results.

### *Double Patenting*

**10.** The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-82 are rejected under the judicially created doctrine of obviousness-type

*double patenting* as being unpatentable over claims 1-11 and 13-21 of U.S. Patent No. 6,352,862

B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: an analytical test device comprising a housing having disposed

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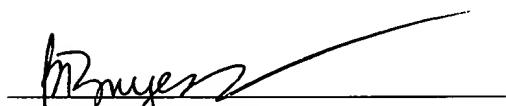
therein a liquid sample application member, a macroporous body having labeled reagent therein, positioned to receive liquid sample from the sample application member and a dry porous carrier strip downstream of the macroporous body, said carrier strip including detection zones for detecting either one or a plurality of analytes.

*Conclusion*

**11.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
\_\_\_\_\_  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641  
July 25, 2002